

March 27, 1999

Dockets Management Branch (HFA-305)  
Food and Drug Administration 6913 '99 MAR 30 P1:56  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Subject: FDA-Docket No. 98N-1265

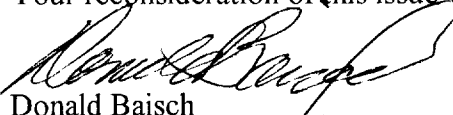
To whom it may concern:

I suffer with Celiac Disease. This is a non-contagious auto-immune condition that causes me to become ill if I eat anything containing or derived from wheat, oats, barley, or rye. Malt is usually derived from barley.

Many over the counter and prescription medications contain ingredients which are harmful to me, including excipients, such as stabilizers, preservatives, colorings, flavorings, sweeteners, binders, dilutants, disintegrants, lubricants, coatings, additives and inert agents. If I need an over the counter or prescription medication, I must do extensive research to see if it contains anything harmful to me. Several times I haven't found a product available commercially or from my HMO. As a result I have had to have a product custom made. Stokes Pharmacy, in New Jersey, is one place where I can get a custom replacement for a product that would otherwise be harmful to me.

If your subject restriction were to be implemented, then a safe source of both over the counter and prescription medications will be denied to me. More important these sources will be denied to the thousands of other people who have dietary restrictions and allergies.

Your reconsideration of this issue would be appreciated.

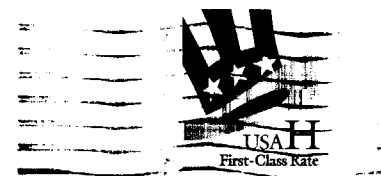
  
Donald Baisch  
528 Sycamore Avenue  
Glendora, CA 91741

c: Rep. David Dreier, Cannon House Bldg, Rm 411, Washington, DC 20515  
Sen. Barbara Boxer, Hart Senate Bldg, #112, Washington, DC 20510  
Sen. Dianne Feinstein, Hart Senate Bldg., #331, Washington, DC 20510

98N-1265

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